IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION

UNITED STATES OF AMERICA *ex rel.* JOHN DAVID FOSTER and JOHN DAVID FOSTER, Individually	§	
Plaintiffs,	§	CIVIL ACTION NO. 1:00CV-246
VS.	§	Unsealed on 10-24-02
WARNER-LAMBERT CO.	§	Order #34
Defendant.	§	

FILED UNDER SEAL

PLAINTIFFS' ORIGINAL COMPLAINT PURSUANT TO 31 U.S.C. §§ 3729-3732, FEDERAL FALSE CLAIMS ACT

The United States of American, by and through *qui tam* Relator, John David Foster, brings this action under 31 U.S.C. §§ 3729-3732 (the "False Claims Act" attached as Exhibit A) to recovery all damages, penalties and other remedies established by the False Claims Act on behalf of the United States and himself and would show the following:

PARTIES

1. John David Foster, "Relator/Plaintiff", brings this *qui tam* claim as Relator on behalf of the United States of America ("United States"), and individually.

2. Parke-Davis is a division of Warner-Lambert Co. Warner-Lambert Co. ("Defendant") is a corporation incorporated in the State of Delaware and doing business in the Eastern District of Texas. Defendant may be served by serving its registered agent in the State of Texas: C.T. Corp. Systems, 350 N. St. Paul Street, Dallas, Texas 75201.

JURISDICTION AND VENUE

3. Jurisdiction and venue are proper in this Court for the following reasons:

a. Jurisdiction for this Court exists pursuant to the False Claims Act (31 U.S.C. § 3730(b)(1) and 31 U.S.C. § 3732(a)) because Relator's claims seek remedies on behalf of the United States for Defendant's multiple violations of 31 U.S.C. § 3729 some of which occurred in the Eastern District of Texas, and because the Defendant transacts other business within the Eastern District of Texas.

b. Venue exists in the United States District Court for the Eastern District of Texas pursuant to 31 U.S.C. § 3730(b)(1) because Defendant is qualified to do business in the State of Texas and conducts business within the State of Texas and within the Eastern District.

FACTUAL BACKGROUND

4. Parke-Davis manufactures and sells pharmaceutical drugs. It currently is a division of Warner Lambert Co., one of the world's largest pharmaceutical companies.

5. In September 1996, Foster began working for Parke-Davis as a Medical Affairs Liaison in its Medical and Scientific Affairs Department. Prior to that time, Foster had spent nine years with Merck Co., five of those years as a Manager of Medical Affairs, and four years as a Sales Representative.

6. In July 1998, Foster was promoted by Parke-Davis to the position of National Account Manager for accounts in Texas and Louisiana. In this position, Foster was responsible for selling pharmaceuticals to managed care organizations in Texas and Louisiana.

7. One of Foster's principle goals as a National Account Manager was to enter into contracts with health maintenance organizations (HMOs) that provided for unrestricted formulary status for Parke-Davis products.

8. Unrestricted formulary status for a drug permits a member of an HMO or other managed care organization to purchase that drug for a small co-payment, usually between $5 to $10. Without that status, physicians cannot freely write prescriptions for such drugs, and patients would have to pay a much higher percentage of the drug's cost. For the most part, unrestricted formulary status is essential to selling a particular drug through a managed care organization.

9. As National Account Manager, Foster's immediate supervisor was Mike Meadows. Meadows is one of five Directors of Parke-Davis' Health Care Management Department. In that position, Meadows is responsible for overseeing and selling pharmaceuticals to managed care organizations in Texas, Louisiana, Arkansas, Nebraska, Oklahoma, Kansas, Missouri, Colorado, and New Mexico.

10. Soon after Foster began his position as National Account Manager, he became aware of several attempts by Meadows and other employees to improperly influence decision makers at managed care organizations in exchange for better formulary status.

11. One incident involved Ochsner Health Plan ("OHP"), a large HMO operating in Louisiana and eastern Texas, and the drug known as Rezulin. Rezulin was a new medication used for the treatment of diabetes.

12. During meetings on or about June 18 and June 29, 1998, Rod Howald of Parke-Davis offered OHP $108,000 in funding in exchange for Rezulin obtaining unrestricted formulary status.

13. OHP chose not to accept that offer, presumably because of several well-publicized deaths associated with taking the drug. Since that time, Warner-Lambert has pulled the drug off the market due to health concerns.

14. The following month, at a meeting with OHP representatives, a pharmacist at OHP advised Foster that OHP viewed the proposed funding on the Rezulin offer as improper and cautioned Foster not to participate in further efforts to "buy" formulary status for a drug.

15. Soon after this meeting, Foster shared OHP's concerns with Meadows. Meadows, however, was unfazed by these concerns, and even boasted to Foster that this particular "incentive" was his idea and that he expected a 4:1 return on all gifts, grants or donations to HMOs. This "incentive" is a violation of 42 U.S.C. § 1320a - 7b(b) ("The Anti-Kickback Statute" is attached as Exhibit B).

16. Parke-Davis' best-selling drug is Lipitor. Lipitor is designed to lower cholesterol levels and the risk of heart attacks.

17. Last year, Parke-Davis sold over $4 billion of Lipitor, making it one of the nation's top three selling drugs.

18. On January 28, 1999, Meadows and Foster met with medical directors and pharmacists of OHP to discuss formulary status for Lipitor. At the meeting, Meadows offered OHP up to $679,000 in various incentives in exchange for unrestricted formulary status for the drug. The majority of this offer was outlined in the"Parke-Davis/Oschner Health Plan Partnership Proposal" ("Partnership Proposal"), which was distributed at the meeting. (A copy of this proposal is attached as Exhibit C.) The offer had six components:

1) OHP was offered a 15% rebate on the list price;

2) OHP was offered $200,000 in immediate funding for a so-called Cholesterol Education & Management program;

3) Parke-Davis offered to pay OHP $50,000 per year for three years to underwrite the salaries of OHP pharmacists;

4) Parke-Davis offered to guarantee a minimum of $25,000 per year for three years in continuing education classes for OHP physicians and pharmacists;

5) Parke-Davis offered to underwrite the total cost of a disease management program. Parke-Davis estimated the cost of the program to be between $180,000 to $200,000, and guaranteed at least $150,000 for the program; and

6) Parke-Davis offered to provide marketing services for OHP's health services.[1]

19. Excluding the rebates, the financial incentives totaled $679,000, with $529,000 to be distributed in the first year, and $75,000 to be paid in cash each year for the next two years. OHP accepted the proposal on February 4, 1999 and placed Lipitor on OHP's formulary as an unrestricted drug. A contract retroactive to January 1, 1999 was signed in March 1999. This agreement is a violation of the Anti-Kickback Statute.

20. After the execution of the March 1999 contract, OHP's rebate was calculated retroactively back to January 1, 1999, the first component of the Partnership Proposal.

21. In April of 1999, OHP received the $200,000 for the second component of the Partnership Proposal.

22. In March of 1999, OHP received the $50,000 for the third component of the Partnership Proposal.

23. OHP has requested the 1999 payment for the fourth component of the Partnership Proposal, the $25,000 for continuing education classes.

24. OHP informed Parke-Davis that due to a conflict with a competing program by Pfizer, OHP would not be requesting the money for the disease management program, the fifth element of the Partnership Proposal.

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[1]The marketing services came in the form of $4000 cash, and the use of Parke-Davis' personnel and a marketing bus called the Lipivan for four days. The estimated cost per day for the van is $25,000. If the expenses are divided 50/50 between Parke-Davis and OHP, the estimated value to OHP is $54,000.

25. Parke-Davis satisfied the sixth component of the agreement by providing cash, personnel and the Lipivan in March of 1999, for marketing of OHP's health services.

26. In 1990, the federal government enacted a number of laws designed to ensure that government agencies received the lowest possible price on various goods and services it purchased. Among those laws was 42 U.S.C. § 1396r-8, entitled "Payment for covered outpatient drugs" (attached as Exhibit D), which applies to prescription drugs. With respect to "single source" or "innovator multiple source" drugs, such as Lipitor and Rezulin, the government is supposed to pay the lower of the "best price" or the average manufacturer price less 15.1%. Exhibit D, § (c). "Best price" is defined as the "lowest price available from the manufacturer" and includes "cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates." If the government did not receive that price, the manufacturer is required to periodically rebate the government for amounts overpaid. Exhibit D, §§ (c)(C).

27. In the two instances described above, Parke-Davis offered to OHP a price that was significantly lower than the price paid by the federal government.

28. With respect to Lipitor, considering all of the incentives offered to OHP and the amounts of Lipitor purchased by OHP, OHP's best price was potentially 46% less than the amount paid by the government. When considering only the incentives that were actually paid to OHP under the Partnership Proposal, OHP's best price was approximately 26% less than the amount paid by the government. If Parke-Davis had complied with the law, the government should have received additional rebates of $39,000,000 to $70,000,000.

29. Lipitor was not the only incident in which Parke-Davis offered these types of incentives and cash payments to obtain unrestricted formulary status for their drugs. As previously mentioned, OHP had been offered $108,000 in rebates to place Rezulin on unrestricted formulary status.

30. After the incidents described above, Foster repeatedly voiced his concerns about potential wrongdoing with Meadows and a number of other persons at the company. As a result of these discussions and Foster's efforts to disclose illegal conduct, Meadows told Foster on November 4, 1999, that he was fired. Parke-Davis, however, has not officially terminated Foster, but has placed him on indefinite administrative leave. His position has been filled by the company and he has been required to return his company computer. By placing Foster on administrative leave, the Defendant has prevented Foster from earning incentive bonuses. These bonuses could have been as much as $30,000 - $40,000 per year. In addition, the Defendant has significantly damaged his reputation in the industry by spreading false information about the reason for his administrative leave.

FALSE CLAIMS ACT

31. This is an action to recover damages and civil penalties on behalf of the United States and Foster arising from the false statements and claims made by Defendant in violation of the Federal False Claims Act, 31 U.S.C. §§ 3729-3732. In addition, it arises from the Defendant's violations of 42 U.S.C. § 1320a-7b(b), the Anti-Kickback Statute.

32. The False Claims Act provides that any person who knowingly submits or causes to be submitted to the United States for payment or approval a false or fraudulent claim is liable to the government for a civil penalty of not less than $5000 and not more than $10,000 for each such

claim,[2] plus three (3) times the amount of damages sustained by the government because of the false claim.

33. The Act allows any persons having knowledge of a false or fraudulent claim against the government to bring an action in Federal District Court for himself and for the United States government and to share in any recovery as authorized by 31 U.S.C. § 3730. John David Foster claims entitlement to a portion of any recovery obtained by the United States as *qui tam* Relator/Plaintiff in this action.

34. Based on these provisions, Foster on behalf of the United States government seeks through this action to recover damages and civil penalties arising from the Defendant's submission of false claims for payment or approval. In this case, such claims were submitted to Medicare, Coast Guard, Department of Defense, Department of Veterans Affairs, Indian Health Services, Public Health Services, and/or Champus for payment for pharmaceuticals. *Qui tam* Relator/Plaintiff believes the United States has suffered significant damages as a result of the Defendant's false claims. The Relator/Plaintiff believes these damages to be in excess of tens of millions of dollars.

35. As required under the False Claims Act *qui tam* Relator/Plaintiff has provided the Attorney General of the United States and the United States Attorney for the Eastern District of Texas a statement of all material evidence and information related to this complaint. That disclosure statement was supported by documentary evidence that verifies the wrong doing.

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[2]A penalty should be assessed against Parke-Davis for each rebate calculation. At a minimum, the Defendant made a rebate calculation for each dosage (3), for each state, for each governmental agency, and for each calender quarter. Assuming there are only the three agencies for which the Relator did calculations, the Defendant would have done 1800 (3 x 50 x 3 x 4) rebate calculations in 1999.

CAUSES OF ACTION

A. Count I - False Claims (31 U.S.C. § 3729).

36. *Qui tam* Relator/Plaintiff realleges and hereby incorporates by reference each and every allegation contained in paragraphs 4 through 36 of this complaint.

37. Based on the acts described above, Defendant knowingly violated one or more of the following:

(a) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;

(c) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;

(d) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government.

38. The United States Government unaware of the falsity of these claims, records, and/or statements made by the Defendant and in reliance on the accuracy thereof, paid the Defendant for the claims.

39. Because of the Defendant's fraudulent conduct, the United States Government did not receive the full rebate to which it was entitled by law in violation of the False Claims Act.

40. Due to the Defendant's conduct, the United States Government has suffered substantial monetary damages.

B. Count II - Retaliation (31 U.S.C. § 3730(h)).

41. *Qui tam* Relator/Plaintiff realleges and incorporates by reference each and every allegation contained in paragraphs 4 through 41 of this complaint.

42. In violation of the False Claims Act § 3730(h), the Defendant took negative employment actions against Relator/Plaintiff in response to his investigation and initiation of this claim.

43. As a result of the Defendant's conduct, the Plaintiff suffered negative employment consequences and has suffered damages.

RELIEF

44. On behalf of the United States Government, the Relator/Plaintiff seeks to receive monetary damages equal to three times that suffered by the United States Government. In addition, the Plaintiff seeks to receive all civil penalties on behalf of the United States Government in accordance with the False Claims Act.

45. The *qui tam* Plaintiff seeks to receive on his own behalf, all monetary damages that he is entitled to for the Defendant's retaliatory conduct against him. In addition, the Plaintiff seek punitive damages in his own behalf.

46. The *qui tam* Relator/Plaintiff seeks to be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(b) of the False Claims Act.

47. The *qui tam* Relator/Plaintiff seeks to be awarded all costs and expenses for this action, including attorneys' fees and court costs.

48. Pre-judgment interest at the highest rate allowed by law.

PRAYER

WHEREFORE, Plaintiff prays that this Court enter judgment on behalf of the Plaintiffs and against the Defendant for the following:

a. Damages in the amount of three (3) time the actual damages suffered by the United States Government as a result of the Defendant's conduct;

b. Civil penalties against the Defendant equal to $10,000 for each violation of 31 U.S.C. 3729;

c. *Qui tam* Relator/Plaintiff be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(b);

d. *Qui tam* Relator/Plaintiff be awarded all costs and expenses of this litigation, including attorneys' fees and costs of court;

e. Pre-judgment interest at the highest rate allowed by law;

f. Relator/Plaintiff's individual damages;

g. Punitive damages to the Relator/Plaintiff for the retaliatory conduct by the Defendant; and

h. All other relief on behalf of the Relator/Plaintiff or the United States Government to which they may be entitled and that the Court deems just and proper.

Respectfully submitted,

BERG ANDROPHY & WILSON

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ATTORNEYS FOR RELATOR/PLAINTIFFS

UNITED STATES CODE ANNOTATED
TITLE 31. MONEY AND FINANCE
SUBTITLE III--FINANCIAL MANAGEMENT
CHAPTER 37--CLAIMS
SUBCHAPTER III--CLAIMS AGAINST THE UNITED STATES GOVERNMENT

Current through P.L. 106-73, approved 10-19-1999

§ 3729. False claims

(a) Liability for certain acts.--Any person who--

(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;

(3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;

(4) has possession, custody, or control of property or money used, or to be used, by the Government and, intending to defraud the Government or willfully to conceal the property, delivers, or causes to be delivered, less property than the amount for which the person receives a certificate or receipt;

(5) authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(6) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge the property; or

(7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government,

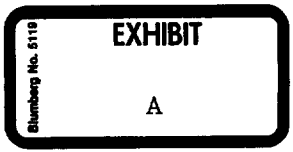
is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person, except that if the court finds that--

(A) the person committing the violation of this subsection furnished officials of the United States responsible for investigating false claims violations with all information known to such person about the violation within 30 days after the date on which the defendant first obtained the information;

(B) such person fully cooperated with any Government investigation of such violation; and

(C) at the time such person furnished the United States with the information about the violation, no criminal prosecution, civil action, or administrative action had commenced under this title with respect to such violation, and the person did not have actual knowledge of the existence of an investigation into such violation;

the court may assess not less than 2 times the amount of damages which the Government sustains because of the act of the person. A person violating this subsection shall also be liable to the United States Government for the costs of a civil action brought to recover any such penalty or damages.



(b) Knowing and knowingly defined.--For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information--

(1) has actual knowledge of the information;

(2) acts in deliberate ignorance of the truth or falsity of the information; or

(3) acts in reckless disregard of the truth or falsity of the information,

and no proof of specific intent to defraud is required.

(c) Claim defined.--For purposes of this section, "claim" includes any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

(d) Exemption from disclosure.--Any information furnished pursuant to subparagraphs (A) through (C) of subsection (a) shall be exempt from disclosure under section 552 of title 5.

(e) Exclusion.--This section does not apply to claims, records, or statements made under the Internal Revenue Code of 1986.

CREDIT(S)

1983 Main Volume

(Pub.L. 97-258, Sept. 13, 1982, 96 Stat. 978.)

1999 Electronic Update

(As amended Pub.L. 99-562, § 2, Oct. 27, 1986, 100 Stat. 3153; Pub.L. 103- 272, § 4(f)(1)(O), July 5, 1994, 108 Stat. 1362.)

<General Materials (GM) - References, Annotations, or Tables>

UNITED STATES CODE ANNOTATED
TITLE 31. MONEY AND FINANCE
SUBTITLE III--FINANCIAL MANAGEMENT
CHAPTER 37--CLAIMS
SUBCHAPTER III--CLAIMS AGAINST THE UNITED STATES GOVERNMENT

Current through P.L. 106-73, approved 10-19-1999

§ 3730. Civil actions for false claims

(a) Responsibilities of the attorney general.--The Attorney General diligently shall investigate a violation under section 3729. If the Attorney General finds that a person has violated or is violating section 3729, the Attorney General may bring a civil action under this section against the person.

(b) Actions by private persons.--(1) A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.

(2) A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure. [FN1] The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information.

(3) The Government may, for good cause shown, move the court for extensions of the time during which the complaint remains under seal under paragraph (2). Any such motions may be supported by affidavits or other submissions in camera. The defendant shall not be required to respond to any complaint filed under this section until 20 days after the complaint is unsealed and served upon the defendant pursuant to Rule 4 of the Federal Rules of Civil Procedure.

(4) Before the expiration of the 60-day period or any extensions obtained under paragraph (3), the Government shall--

(A) proceed with the action, in which case the action shall be conducted by the Government; or

(B) notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.

(5) When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.

(c) Rights of the parties to Qui Tam actions.--(1) If the Government proceeds with the action, it shall have the primary responsibility for prosecuting the action, and shall not be bound by an act of the person bringing the action. Such person shall have the right to continue as a party to the action, subject to the limitations set forth in paragraph (2).

(2)(A) The Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion.

(B) The Government may settle the action with the defendant notwithstanding the objections of the person initiating the action if the court determines, after a hearing, that the proposed settlement is fair, adequate, and reasonable under all the circumstances. Upon a showing of good cause, such hearing may be held in camera.

(C) Upon a showing by the Government that unrestricted participation during the course of the litigation by the person initiating the action would interfere with or unduly delay the Government's prosecution of the case, or would be repetitious, irrelevant, or for purposes of harassment, the court may, in its discretion, impose limitations on the person's participation, such as--

(i) limiting the number of witnesses the person may call;

(ii) limiting the length of the testimony of such witnesses;

(iii) limiting the person's cross-examination of witnesses; or

(iv) otherwise limiting the participation by the person in the litigation.

(D) Upon a showing by the defendant that unrestricted participation during the course of the litigation by the person initiating the action would be for purposes of harassment or would cause the defendant undue burden or unnecessary expense, the court may limit the participation by the person in the litigation.

(3) If the Government elects not to proceed with the action, the person who initiated the action shall have the right to conduct the action. If the Government so requests, it shall be served with copies of all pleadings filed in the action and shall be supplied with copies of all deposition transcripts (at the Government's expense). When a person proceeds with the action, the court, without limiting the status and rights of the person initiating the action, may nevertheless permit the Government to intervene at a later date upon a showing of good cause.

(4) Whether or not the Government proceeds with the action, upon a showing by the Government that certain actions of discovery by the person initiating the action would interfere with the Government's investigation or prosecution of a criminal or civil matter arising out of the same facts, the court may stay such discovery for a period of not more than 60 days. Such a showing shall be conducted in camera. The court may extend the 60-day period upon a further showing in camera that the Government has pursued the criminal or civil investigation or proceedings with reasonable diligence and any proposed discovery in the civil action will interfere with the ongoing criminal or civil investigation or proceedings.

(5) Notwithstanding subsection (b), the Government may elect to pursue its claim through any alternate remedy available to the Government, including any administrative proceeding to determine a civil money penalty. If any such alternate remedy is pursued in another proceeding, the person initiating the action shall have the same rights in such proceeding as such person would have had if the action had continued under this section. Any finding of fact or conclusion of law made in such other proceeding that has become final shall be conclusive on all parties to an action under this section. For purposes of the preceding sentence, a finding or conclusion is final if it has been finally determined on appeal to the appropriate court of the United States, if all time for filing such an appeal with respect to the finding or conclusion has expired, or if the finding or conclusion is not subject to judicial review.

(d) Award to Qui Tam plaintiff.--(1) If the Government proceeds with an action brought by a person under subsection (b), such person shall, subject to the second sentence of this paragraph, receive at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim, depending upon the extent to which the person substantially contributed to the prosecution of the action. Where the action is one which the court finds to be based primarily on disclosures of specific information (other than information provided by the person bringing the action) relating to allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, the court may award such sums as it considers appropriate, but in no case more than 10 percent of the proceeds, taking into account the significance of the information and the role of the person bringing the action in advancing the case to litigation. Any payment to a person under the first or second sentence of this paragraph shall be made from the proceeds. Any such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

(2) If the Government does not proceed with an action under this section, the person bringing the action or settling the

claim shall receive an amount which the court decides is reasonable for collecting the civil penalty and damages. The amount shall be not less than 25 percent and not more than 30 percent of the proceeds of the action or settlement and shall be paid out of such proceeds. Such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

(3) Whether or not the Government proceeds with the action, if the court finds that the action was brought by a person who planned and initiated the violation of section 3729 upon which the action was brought, then the court may, to the extent the court considers appropriate, reduce the share of the proceeds of the action which the person would otherwise receive under paragraph (1) or (2) of this subsection, taking into account the role of that person in advancing the case to litigation and any relevant circumstances pertaining to the violation. If the person bringing the action is convicted of criminal conduct arising from his or her role in the violation of section 3729, that person shall be dismissed from the civil action and shall not receive any share of the proceeds of the action. Such dismissal shall not prejudice the right of the United States to continue the action, represented by the Department of Justice.

(4) If the Government does not proceed with the action and the person bringing the action conducts the action, the court may award to the defendant its reasonable attorneys' fees and expenses if the defendant prevails in the action and the court finds that the claim of the person bringing the action was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment.

(e) Certain actions barred.--(1) No court shall have jurisdiction over an action brought by a former or present member of the armed forces under subsection (b) of this section against a member of the armed forces arising out of such person's service in the armed forces.

(2)(A) No court shall have jurisdiction over an action brought under subsection (b) against a Member of Congress, a member of the judiciary, or a senior executive branch official if the action is based on evidence or information known to the Government when the action was brought.

(B) For purposes of this paragraph, "senior executive branch official" means any officer or employee listed in paragraphs (1) through (8) of section 101(f) of the Ethics in Government Act of 1978 (5 U.S.C.App.).

(3) In no event may a person bring an action under subsection (b) which is based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the Government is already a party.

(4)(A) No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

(B) For purposes of this paragraph, "original source" means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

(f) Government not liable for certain expenses.--The Government is not liable for expenses which a person incurs in bringing an action under this section.

(g) Fees and expenses to prevailing defendant.--In civil actions brought under this section by the United States, the provisions of section 2412(d) of title 28 shall apply.

(h) Any employee who is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment by his or her employer because of lawful acts done by the employee on behalf of the employee or others in furtherance of an action under this section, including investigation for, initiation of, testimony for, or assistance in an action filed or to be filed under this section, shall be entitled to all relief necessary to make the employee whole. Such relief shall include reinstatement with the same seniority status such employee

would have had but for the discrimination, 2 times the amount of back pay, interest on the back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys' fees. An employee may bring an action in the appropriate district court of the United States for the relief provided in this subsection.

CREDIT(S)

1983 Main Volume

(Pub.L. 97-258, Sept. 13, 1982, 96 Stat. 978.)

1999 Electronic Update

(As amended Pub.L. 99-562, §§ 3, 4, Oct. 27, 1986, 100 Stat. 3154, 3157; Pub.L. 100-700, § 9, Nov. 19, 1988, 102 Stat. 4638; Pub.L. 101-280, § 10(a), May 4, 1990, 104 Stat. 162; Pub.L. 103-272, § 4(f)(1)(P), July 5, 1994, 108 Stat. 1362.)

[FN1] See, now, Rule 4(i) of the Federal Rules of Civil Procedure.

<General Materials (GM) - References, Annotations, or Tables>

UNITED STATES CODE ANNOTATED
TITLE 31. MONEY AND FINANCE
SUBTITLE III--FINANCIAL MANAGEMENT
CHAPTER 37--CLAIMS
SUBCHAPTER III--CLAIMS AGAINST THE UNITED STATES GOVERNMENT

Current through P.L. 106-73, approved 10-19-1999

§ 3731. False claims procedure

(a) A subpena requiring the attendance of a witness at a trial or hearing conducted under section 3730 of this title may be served at any place in the United States.

(b) A civil action under section 3730 may not be brought--

(1) more than 6 years after the date on which the violation of section 3729 is committed, or

(2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed,

whichever occurs last.

(c) In any action brought under section 3730, the United States shall be required to prove all essential elements of the cause of action, including damages, by a preponderance of the evidence.

(d) Notwithstanding any other provision of law, the Federal Rules of Criminal Procedure, or the Federal Rules of Evidence, a final judgment rendered in favor of the United States in any criminal proceeding charging fraud or false statements, whether upon a verdict after trial or upon a plea of guilty or nolo contendere, shall estop the defendant from denying the essential elements of the offense in any action which involves the same transaction as in the criminal proceeding and which is brought under subsection (a) or (b) of section 3730.

CREDIT(S)

1983 Main Volume

(Pub.L. 97-258, Sept. 13, 1982, 96 Stat. 979.)

1999 Electronic Update

(As amended Pub.L. 99-562, § 5, Oct. 27, 1986, 100 Stat. 3158.)

<General Materials (GM) - References, Annotations, or Tables>

UNITED STATES CODE ANNOTATED
TITLE 31. MONEY AND FINANCE
SUBTITLE III--FINANCIAL MANAGEMENT
CHAPTER 37--CLAIMS
SUBCHAPTER III--CLAIMS AGAINST THE UNITED STATES GOVERNMENT

Current through P.L. 106-73, approved 10-19-1999

§ 3732. False claims jurisdiction

(a) Actions under section 3730.--Any action under section 3730 may be brought in any judicial district in which the defendant or, in the case of multiple defendants, any one defendant can be found, resides, transacts business, or in which any act proscribed by section 3729 occurred. A summons as required by the Federal Rules of Civil Procedure shall be issued by the appropriate district court and served at any place within or outside the United States.

(b) Claims under state law.--The district courts shall have jurisdiction over any action brought under the laws of any State for the recovery of funds paid by a State or local government if the action arises from the same transaction or occurrence as an action brought under section 3730.

CREDIT(S)

1999 Electronic Update

(Added Pub.L. 99-562, § 6(a), Oct. 27, 1986, 100 Stat. 3158.)

<General Materials (GM) - References, Annotations, or Tables>

HISTORICAL AND STATUTORY NOTES

References in Text

The Federal Rules of Civil Procedure, referred to in subsec. (a), are classified to Title 28, Judiciary and Judicial Procedure.

Legislative History

For legislative history and purpose of Pub.L. 99-562, see 1986 U.S. Code Cong. and Adm. News, p. 5266.

UNITED STATES CODE ANNOTATED
TITLE 42. THE PUBLIC HEALTH AND WELFARE
CHAPTER 7--SOCIAL SECURITY
SUBCHAPTER XI--GENERAL PROVISIONS, PEER REVIEW, AND ADMINISTRATIVE SIMPLIFICATION
PART A--GENERAL PROVISIONS

Current through P.L. 106-73, approved 10-19-1999

§ 1320a-7b. Criminal penalties for acts involving Federal health care programs

(a) Making or causing to be made false statements or representations

Whoever--

(1) knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under a Federal health care program (as defined in subsection (f) of this section),

(2) at any time knowingly and willfully makes or causes to be made any false statement or representation of a material fact for use in determining rights to such benefit or payment,

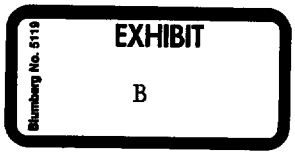
(3) having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment, or (B) the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment, conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized,

(4) having made application to receive any such benefit or payment for the use and benefit of another and having received it, knowingly and willfully converts such benefit or payment or any part thereof to a use other than for the use and benefit of such other person,

(5) presents or causes to be presented a claim for a physician's service for which payment may be made under a Federal health care program and knows that the individual who furnished the service was not licensed as a physician, or

(6) for a fee knowingly and willfully counsels or assists an individual to dispose of assets (including by any transfer in trust) in order for the individual to become eligible for medical assistance under a State plan under subchapter XIX of this chapter, if disposing of the assets results in the imposition of a period of ineligibility for such assistance under section 1396p(c) of this title,

shall (i) in the case of such a statement, representation, concealment, failure, or conversion by any person in connection with the furnishing (by that person) of items or services for which payment is or may be made under the program, be guilty of a felony and upon conviction thereof fined not more than $25,000 or imprisoned for not more than five years or both, or (ii) in the case of such a statement, representation, concealment, failure, conversion, or provision of counsel or assistance by any other person, be guilty of a misdemeanor and upon conviction thereof fined not more than $10,000 or imprisoned for not more than one year, or both. In addition, in any case where an individual who is otherwise eligible for assistance under a Federal health care program is convicted of an offense under the preceding provisions of this subsection, the administrator of such program may at its option (notwithstanding any other provision of such program) limit, restrict, or suspend the eligibility of that individual for such period (not exceeding one year) as it deems appropriate; but the imposition of a limitation, restriction, or suspension with respect to the eligibility of any individual under this sentence shall not affect the eligibility of any other person for assistance under the plan, regardless of the relationship between that individual and such other person.



(b) Illegal remunerations

(1) whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind--

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

(2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person--

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

(3) Paragraphs (1) and (2) shall not apply to--

(A) a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program;

(B) any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services;

(C) any amount paid by a vendor of goods or services to a person authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services reimbursed under a Federal health care program if--

(i) the person has a written contract, with each such individual or entity, which specifies the amount to be paid the person, which amount may be a fixed amount or a fixed percentage of the value of the purchases made by each such individual or entity under the contract, and

(ii) in the case of an entity that is a provider of services (as defined in section 1395x(u) of this title), the person discloses (in such form and manner as the Secretary requires) to the entity and, upon request, to the Secretary the amount received from each such vendor with respect to purchases made by or on behalf of the entity;

(D) a waiver of any coinsurance under part B of subchapter XVIII of this chapter by a Federally qualified health care center with respect to an individual who qualifies for subsidized services under a provision of the Public Health Service Act [42 U.S.C.A. § 201 et seq.];

(E) any payment practice specified by the Secretary in regulations promulgated pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987; and

(F) any remuneration between an organization and an individual or entity providing items or services, or a combination thereof, pursuant to a written agreement between the organization and the individual or entity if the

organization is an eligible organization under section 1395mm of this title or if the written agreement, through a risk-sharing arrangement, places the individual or entity at substantial financial risk for the cost or utilization of the items or services, or a combination thereof, which the individual or entity is obligated to provide.

(c) False statements or representations with respect to condition or operation of institutions

Whoever knowingly and willfully makes or causes to be made, or induces or seeks to induce the making of, any false statement or representation of a material fact with respect to the conditions or operation of any institution, facility, or entity in order that such institution, facility, or entity may qualify (either upon initial certification or upon recertification) as a hospital, critical access hospital, skilled nursing facility, nursing facility, intermediate care facility for the mentally retarded, home health agency, or other entity (including an eligible organization under section 1395mm(b) of this title) for which certification is required under subchapter XVIII of this chapter or a State health care program (as defined in section 1320a-7(h) of this title), or with respect to information required to be provided under section 1320a-3a of this title, shall be guilty of a felony and upon conviction thereof shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

(d) Illegal patient admittance and retention practices

Whoever knowingly and willfully--

(1) charges, for any service provided to a patient under a State plan approved under subchapter XIX of this chapter, money or other consideration at a rate in excess of the rates established by the State (or, in the case of services provided to an individual enrolled with a medicaid managed care organization under subchapter XIX of this chapter under a contract under section 1396b(m) of this title or under a contractual, referral, or other arrangement under such contract, at a rate in excess of the rate permitted under such contract), or

(2) charges, solicits, accepts, or receives, in addition to any amount otherwise required to be paid under a State plan approved under subchapter XIX of this chapter, any gift, money, donation, or other consideration (other than a charitable, religious, or philanthropic contribution from an organization or from a person unrelated to the patient)--

(A) as a precondition of admitting a patient to a hospital, nursing facility, or intermediate care facility for the mentally retarded, or

(B) as a requirement for the patient's continued stay in such a facility,

when the cost of the services provided therein to the patient is paid for (in whole or in part) under the State plan,

shall be guilty of a felony and upon conviction thereof shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

(e) Violation of assignment terms

Whoever accepts assignments described in section 1395u(b)(3)(B)(ii) of this title or agrees to be a participating physician or supplier under section 1395u(h)(1) of this title and knowingly, willfully, and repeatedly violates the term of such assignments or agreement, shall be guilty of a misdemeanor and upon conviction thereof shall be fined not more than $2,000 or imprisoned for not more than six months, or both.

(f) "Federal health care program" defined

For purposes of this section, the term "Federal health care program" means--

(1) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the health insurance program under chapter 89 of Title 5); or

(2) any State health care program, as defined in section 1320a-7(h) of this title.

CREDIT(S)

1999 Electronic Update

(Aug. 14, 1935, c. 531, Title XI, § 1128B, formerly Title XVIII, § 1877(d), and Title XIX, § 1909, as added and amended Oct. 30, 1972, Pub.L. 92-603, Title II, §§ 242(c), 278(b)(9), 86 Stat. 1419, 1454; Oct. 25, 1977, Pub.L. 95-142, § 4(a), (b), 91 Stat. 1179, 1181; Dec. 5, 1980, Pub.L. 96-499, Title IX, § 917, 94 Stat. 2625; July 18, 1984, Pub.L. 98-369, Div. B, Title III, § 2306(f)(2), 98 Stat. 1073; renumbered Title XI, § 1128B and amended Aug. 18, 1987, Pub.L. 100-93, §§ 4(a) to (d), 14(b), 101 Stat. 688, 689, 697; Dec. 22, 1987, Pub.L. 100-203, Title IV, §§ 4039(a), 4211(h)(7), 101 Stat. 1330-81, 1330-206; July 1, 1988, Pub.L. 100-360, Title IV, § 411(a)(3)(A), (B)(i), 102 Stat. 768; Dec. 19, 1989, Pub.L. 101-239, Title VI, § 6003(g)(3)(D)(ii), 103 Stat. 2153; Nov. 5, 1990, Pub.L. 101-508, Title IV, §§ 4161(a)(4), 4164(b)(2), 104 Stat. 1388- 94, 1388-102; Oct. 31, 1994, Pub.L. 103-432, Title I, § 133(a)(2), 108 Stat. 4421; Aug. 21, 1996, Pub.L. 104-191, Title II, §§ 204(a), 216(a), 217, 110 Stat. 1999, 2007, 2008; Aug. 5, 1997, Pub.L. 105-33, Title IV, §§ 4201(c)(1), 4704(b), 4734, 111 Stat. 373, 498, 522.)

<General Materials (GM) - References, Annotations, or Tables>

PARKE-DAVIS/OCHSNER HEALTH PLAN
PARTNERSHIP PROPOSAL

PRODUCT: LIPITOR (Atorvastatin Calcium tablets)

~~DOSAGE STRENGTHS: 10mg, 20mg, 40mg~~

CONTRACT TERM: 1/1/99 - 12/31/2001 (3 years)

CONTRACT DISCOUNTS:
Rx market share performance based on OHP Lipitor market share by quarter.
(Market defined as HMGs only/Lipitor, Pravachol, Zocor, Mevacor, Lescol, Baycol)

Rebates:	(As of 1/28/99)
~~OHP base is 27.5%~~	~~25% off AWP/5% off catalog~~
27.6% - 39.9%:	30% off AWP/10% off catalog
>40.0%:	35% off AWP/15% off catalog

CONDITIONS:
1. Lipitor (all strengths) must be listed on OHP formulary with no restrictions
2. If OHP formulary suggests preferred or primary product(s). Lipitor must be included as a preferred or primary product of equal status.
3. Stand alone contract

ADDITIONAL FINANICAL SUPPORT:
1. $200,000 check for Cholesterol Education & management will be given to OHP upon acceptance of partnership.
2. Parke-Davis will support OHP pharmacy/DSM programs by underwriting the salary of additional pharmacy personnel (TBD). $50,000 per year /total of $150,000.
3. Parke-Davis will guarantee a minimum of $25,000 in CE/CME programs/support for OHP Pharmacy and Physicians per year.
4. Parke-Davis will underwrite total cost of ProMedex Patient Disease management program for Diabetes. Program could include CHF and Depression. Cost of project is estimated @ $180,000 - $200,000. Minimum is $150,000.

Total Partnership dollar value to OHP	Year 1	Year 2	Year 3
1. Minim rebates *	$225,000(24%)	$700,000(40%)	$875,000(50%)
2. ~~Cholesterol Management funding~~	~~$200,000~~	0	0
3. Pharmacy FT funding:	$ 50,000	$ 50,000	$ 50,000
4. CE/CME Educational programs:	$ 25,000	$ 25,000	$ 25,000
5. Promedex patient management project:	$180,000	0	0
TOTAL:	$680,000	$775,000	$ 950,000
TOTAL CONTRACT OHP REVENUE:			$2,405,000

- Assumptions based on current OHP HMG approx. dollar market

DRAFT ONLY

This document has been amended. Use UPDATE.
See SCOPE for more information.

UNITED STATES CODE ANNOTATED
TITLE 42. THE PUBLIC HEALTH AND WELFARE
CHAPTER 7--SOCIAL SECURITY
SUBCHAPTER XIX--GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

Current through P.L. 106-73, approved 10-19-1999

§ 1396r-8. Payment for covered outpatient drugs

(a) Requirement for rebate agreement

(1) In general

In order for payment to be available under section 1396b(a) of this title for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) of this section with the Secretary, on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a manufacturer), and must meet the requirements of paragraph (5) (with respect to drugs purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992) and paragraph (6). Any agreement between a State and a manufacturer prior to April 1, 1991, shall be deemed to have been entered into on January 1, 1991, and payment to such manufacturer shall be retroactively calculated as if the agreement between the manufacturer and the State had been entered into on January 1, 1991. If a manufacturer has not entered into such an agreement before March 1, 1991, such an agreement, subsequently entered into, shall not be effective until the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

(2) Effective date

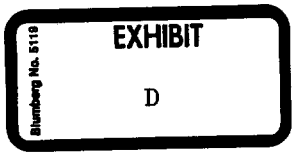
Paragraph (1) shall first apply to drugs dispensed under this subchapter on or after January 1, 1991.

(3) Authorizing payment for drugs not covered under rebate agreements

Paragraph (1), and section 1396b(i)(10)(A) of this title, shall not apply to the dispensing of a single source drug or innovator multiple source drug if (A)(i) the State has made a determination that the availability of the drug is essential to the health of beneficiaries under the State plan for medical assistance; (ii) such drug has been given a rating of 1-A by the Food and Drug Administration; and (iii)(I) the physician has obtained approval for use of the drug in advance of its dispensing in accordance with a prior authorization program described in subsection (d) of this section, or (II) the Secretary has reviewed and approved the State's determination under subparagraph (A); or (B) the Secretary determines that in the first calendar quarter of 1991, there were extenuating circumstances.

(4) Effect on existing agreements

In the case of a rebate agreement in effect between a State and a manufacturer on November 5, 1990, such agreement, for the initial agreement period specified therein, shall be considered to be a rebate agreement in compliance with this section with respect to that State, if the State agrees to report to the Secretary any rebates paid pursuant to the agreement and such agreement provides for a minimum aggregate rebate of 10 percent of the State's total expenditures under the State plan for coverage of the manufacturer's drugs under this subchapter. If, after the initial agreement period, the State establishes to the satisfaction of the Secretary that an agreement in effect on November 5, 1990, provides for rebates that are at least as large as the rebates otherwise required under this section, and the State agrees to report any rebates under the agreement to the Secretary, the agreement shall be considered to be a rebate agreement in compliance with the section for the renewal periods of such agreement.



(5) Limitation on prices of drugs purchased by covered entities

(A) Agreement with Secretary

A manufacturer meets the requirements of this paragraph if the manufacturer has entered into an agreement with the Secretary that meets the requirements of section 256b of this title with respect to covered outpatient drugs purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992.

(B) Covered entity defined

In this subsection, the term "covered entity" means an entity described in section 256b(a)(4) of this title.

(C) Establishment of alternative mechanism to ensure against duplicate discounts or rebates

If the Secretary does not establish a mechanism under section 256b(a)(5)(A) of this title within 12 months of November 4, 1992, the following requirements shall apply:

(i) Entities

Each covered entity shall inform the single State agency under section 1396a(a)(5) of this title when it is seeking reimbursement from the State plan for medical assistance described in section 1396d(a)(12) of this title with respect to a unit of any covered outpatient drug which is subject to an agreement under section 256b(a) of this title.

(ii) State agency

Each such single State agency shall provide a means by which a covered entity shall indicate on any drug reimbursement claims form (or format, where electronic claims management is used) that a unit of the drug that is the subject of the form is subject to an agreement under section 256b of this title, and not submit to any manufacturer a claim for a rebate payment under subsection (b) of this section with respect to such a drug.

(D) Effect of subsequent amendments

In determining whether an agreement under subparagraph (A) meets the requirements of section 256b of this title, the Secretary shall not take into account any amendments to such section that are enacted after November 4, 1992.

(E) Determination of compliance

A manufacturer is deemed to meet the requirements of this paragraph if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of section 256b of this title (as in effect immediately after November 4, 1992) and would have entered into an agreement under such section (as such section was in effect at such time), but for a legislative change in such section after November 4, 1992.

(6) Requirements relating to master agreements for drugs procured by Department of Veterans Affairs and certain other Federal agencies

(A) In general

A manufacturer meets the requirements of this paragraph if the manufacturer complies with the provisions of section 8126 of Title 38, including the requirement of entering into a master agreement with the Secretary of Veterans Affairs under such section.

(B) Effect of subsequent amendments

In determining whether a master agreement described in subparagraph (A) meets the requirements of section 8126 of

Title 38, the Secretary shall not take into account any amendments to such section that are enacted after November 4, 1992.

(C) Determination of compliance

A manufacturer is deemed to meet the requirements of this paragraph if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of section 8126 of Title 38, (as in effect immediately after November 4, 1992) and would have entered into an agreement under such section (as such section was in effect at such time), but for a legislative change in such section after November 4, 1992.

(b) Terms of rebate agreement

(1) Periodic rebates

(A) In general

A rebate agreement under this subsection shall require the manufacturer to provide, to each State plan approved under this subchapter, a rebate for a rebate period in an amount specified in subsection (c) of this section for covered outpatient drugs of the manufacturer dispensed after December 31, 1990, for which payment was made under the State plan for such period. Such rebate shall be paid by the manufacturer not later than 30 days after the date of receipt of the information described in paragraph (2) for the period involved.

(B) Offset against medical assistance

Amounts received by a State under this section (or under an agreement authorized by the Secretary under subsection (a)(1) of this section or an agreement described in subsection (a)(4) of this section) in any quarter shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1396b(a)(1) of this title.

(2) State provision of information

(A) State responsibility

Each State agency under this subchapter shall report to each manufacturer not later than 60 days after the end of each rebate period and in a form consistent with a standard reporting format established by the Secretary, information on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed after December 31, 1990, for which payment was made under the plan during the period, and shall promptly transmit a copy of such report to the Secretary.

(B) Audits

A manufacturer may audit the information provided (or required to be provided) under subparagraph (A). Adjustments to rebates shall be made to the extent that information indicates that utilization was greater or less than the amount previously specified.

(3) Manufacturer provision of price information

(A) In general

Each manufacturer with an agreement in effect under this section shall report to the Secretary--

(i) not later than 30 days after the last day of each rebate period under the agreement (beginning on or after January 1, 1991), on the average manufacturer price (as defined in subsection (k)(1) of this section) and, (for single source drugs and innovator multiple source drugs), the manufacturer's best price (as defined in subsection (c)(2)(B) of this

section) for covered outpatient drugs for the rebate period under the agreement, and

(ii) not later than 30 days after the date of entering into an agreement under this section on the average manufacturer price (as defined in subsection (k)(1) of this section) as of October 1, 1990 [FN1] for each of the manufacturer's covered outpatient drugs.

(B) Verification surveys of average manufacturer price

The Secretary may survey wholesalers and manufacturers that directly distribute their covered outpatient drugs, when necessary, to verify manufacturer prices reported under subparagraph (A). The Secretary may impose a civil monetary penalty in an amount not to exceed $100,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information. The provisions of section 1320a-7a of this title (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(C) Penalties

(i) Failure to provide timely information

In the case of a manufacturer with an agreement under this section that fails to provide information required under subparagraph (A) on a timely basis, the amount of the penalty shall be increased by $10,000 for each day in which such information has not been provided and such amount shall be paid to the Treasury, and, if such information is not reported within 90 days of the deadline imposed, the agreement shall be suspended for services furnished after the end of such 90-day period and until the date such information is reported (but in no case shall such suspension be for a period of less than 30 days).

(ii) False information

Any manufacturer with an agreement under this section that knowingly provides false information is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law. The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(D) Confidentiality of information

Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph or under an agreement with the Secretary of Veterans Affairs described in subsection (a)(6)(A)(ii) of this section is confidential and shall not be disclosed by the Secretary or the Secretary of Veterans Affairs or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except--

(i) as the Secretary determines to be necessary to carry out this section,

(ii) to permit the Comptroller General to review the information provided, and

(iii) to permit the Director of the Congressional Budget Office to review the information provided.

(4) Length of agreement

(A) In general

A rebate agreement shall be effective for an initial period of not less than 1 year and shall be automatically renewed

for a period of not less than one year unless terminated under subparagraph (B).

(B) Termination

(i) By the Secretary

The Secretary may provide for termination of a rebate agreement for violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 60 days after the date of notice of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

(ii) By a manufacturer

A manufacturer may terminate a rebate agreement under this section for any reason. Any such termination shall not be effective until the calendar quarter beginning at least 60 days after the date the manufacturer provides notice to the Secretary.

(iii) Effectiveness of termination

Any termination under this subparagraph shall not affect rebates due under the agreement before the effective date of its termination.

(iv) Notice to States

In the case of a termination under this subparagraph, the Secretary shall provide notice of such termination to the States within not less than 30 days before the effective date of such termination.

(v) Application to terminations of other agreements

The provisions of this subparagraph shall apply to the terminations of agreements described in section 256b(a)(1) of this title and master agreements described in section 8126(a) of Title 38.

(C) Delay before reentry

In the case of any rebate agreement with a manufacturer under this section which is terminated, another such agreement with the manufacturer (or a successor manufacturer) may not be entered into until a period of 1 calendar quarter has elapsed since the date of the termination, unless the Secretary finds good cause for an earlier reinstatement of such an agreement.

(c) Determination of amount of rebate

(1) Basic rebate for single source drugs and innovator multiple source drugs

(A) In general

Except as provided in paragraph (2), the amount of the rebate specified in this subsection for a rebate period (as defined in subsection (k)(8) of this section) with respect to each dosage form and strength of a single source drug or an innovator multiple source drug shall be equal to the product of--

(i) the total number of units of each dosage form and strength paid for under the State plan in the rebate period (as reported by the State); and

(ii) subject to subparagraph (B)(ii), the greater of--

(I) the difference between the average manufacturer price and the best price (as defined in subparagraph (C)) for the

dosage form and strength of the drug, or

(II) the minimum rebate percentage (specified in subparagraph (B)(i)) of such average manufacturer price,

for the rebate period.

(B) Range of rebates required

(i) Minimum rebate percentage

For purposes of subparagraph (A)(ii)(II), the "minimum rebate percentage" for rebate periods beginning--

(I) after December 31, 1990, and before October 1, 1992, is 12.5 percent;

(II) after September 30, 1992, and before January 1, 1994, is 15.7 percent;

(III) after December 31, 1993, and before January 1, 1995, is 15.4 percent;

(IV) after December 31, 1994, and before January 1, 1996, is 15.2 percent; and

(V) after December 31, 1995, is 15.1 percent.

(ii) Temporary limitation on maximum rebate amount

In no case shall the amount applied under subparagraph (A)(ii) for a rebate period beginning--

(I) before January 1, 1992, exceed 25 percent of the average manufacturer price; or

(II) after December 31, 1991, and before January 1, 1993, exceed 50 percent of the average manufacturer price.

(C) Best price defined

For purposes of this section--

(i) In general

The term "best price" means, with respect to a single source drug or innovator multiple source drug of a manufacturer, the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding--

(I) any prices charged on or after October 1, 1992, to the Indian Health Service, the Department of Veterans Affairs, a State home receiving funds under section 1741 of Title 38, the Department of Defense, the Public Health Service, or a covered entity described in subsection (a)(5)(B) of this section;

(II) any prices charged under the Federal Supply Schedule of the General Services Administration;

(III) any prices used under a State pharmaceutical assistance program; and

(IV) any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government.

(ii) Special rules

The term "best price"--

(I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section);

(II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package; and

(III) shall not take into account prices that are merely nominal in amount.

(2) Additional rebate for single source and innovator multiple source drugs

(A) In general

The amount of the rebate specified in this subsection for a rebate period, with respect to each dosage form and strength of a single source drug or an innovator multiple source drug, shall be increased by an amount equal to the product of--

(i) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period; and

(ii) the amount (if any) by which--

(I) the average manufacturer price for the dosage form and strength of the drug for the period, exceeds

(II) the average manufacturer price for such dosage form and strength for the calendar quarter beginning July 1, 1990 (without regard to whether or not the drug has been sold or transferred to an entity, including a division or subsidiary of the manufacturer, after the first day of such quarter), increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index for September 1990.

(B) Treatment of subsequently approved drugs

In the case of a covered outpatient drug approved by the Food and Drug Administration after October 1, 1990, clause (ii)(II) of subparagraph (A) shall be applied by substituting "the first full calendar quarter after the day on which the drug was first marketed" for "the calendar quarter beginning July 1, 1990" and "the month prior to the first month of the first full calendar quarter after the day on which the drug was first marketed" for "September 1990".

(3) Rebate for other drugs

(A) In general

The amount of the rebate paid to a State for a rebate period with respect to each dosage form and strength of covered outpatient drugs (other than single source drugs and innovator multiple source drugs) shall be equal to the product of--

(i) the applicable percentage (as described in subparagraph (B)) of the average manufacturer price for the dosage form and strength for the rebate period, and

(ii) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period.

(B) Applicable percentage defined

For purposes of subparagraph (A)(i), the "applicable percentage" for rebate periods beginning--

(i) before January 1, 1994, is 10 percent, and

(ii) after December 31, 1993, is 11 percent.

(d) Limitations on coverage of drugs

(1) Permissible restrictions

(A) A State may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5).

(B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if--

(i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6) of this section);

(ii) the drug is contained in the list referred to in paragraph (2);

(iii) the drug is subject to such restrictions pursuant to an agreement between a manufacturer and a State authorized by the Secretary under subsection (a)(1) of this section or in effect pursuant to subsection (a)(4) of this section; or

(iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4).

(2) List of drugs subject to restriction

The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:

(A) Agents when used for anorexia, weight loss, or weight gain.

(B) Agents when used to promote fertility.

(C) Agents when used for cosmetic purposes or hair growth.

(D) Agents when used for the symptomatic relief of cough and colds.

(E) Agents when used to promote smoking cessation.

(F) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

(G) Nonprescription drugs.

(H) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

(I) Barbiturates.

(J) Benzodiazepines.

(3) Update of drug listings

The Secretary shall, by regulation, periodically update the list of drugs or classes of drugs described in paragraph (2) or their medical uses, which the Secretary has determined, based on data collected by surveillance and utilization review programs of State medical assistance programs, to be subject to clinical abuse or inappropriate use.

(4) Requirements for formularies

A State may establish a formulary if the formulary meets the following requirements:

(A) The formulary is developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State (or, at the option of the State, the State's drug use review board established under subsection (g)(3) of this section).

(B) Except as provided in subparagraph (C), the formulary includes the covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under subsection (a) of this section (other than any drug excluded from coverage or otherwise restricted under paragraph (2)).

(C) A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling (or, in the case of a drug the prescribed use of which is not approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.] but is a medically accepted indication, based on information from the appropriate compendia described in subsection (k)(6) of this section), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.

(D) The State plan permits coverage of a drug excluded from the formulary (other than any drug excluded from coverage or otherwise restricted under paragraph (2)) pursuant to a prior authorization program that is consistent with paragraph (5).

(E) The formulary meets such other requirements as the Secretary may impose in order to achieve program savings consistent with protecting the health of program beneficiaries.

A prior authorization program established by a State under paragraph (5) is not a formulary subject to the requirements of this paragraph.

(5) Requirements of prior authorization programs

A State plan under this subchapter may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, with respect to drugs dispensed on or after July 1, 1991, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6) of this section) only if the system providing for such approval--

(A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and

(B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

(6) Other permissible restrictions

A State may impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription or on the number of refills, if such limitations are necessary to discourage waste, and may address instances of fraud or abuse by individuals in any manner authorized under this chapter.

(e) Treatment of pharmacy reimbursement limits

(1) In general

During the period beginning on January 1, 1991, and ending on December 31, 1994--

(A) a State may not reduce the payment limits established by regulation under this subchapter or any limitation described in paragraph (3) with respect to the ingredient cost of a covered outpatient drug or the dispensing fee for such a drug below the limits in effect as of January 1, 1991, and

(B) except as provided in paragraph (2), the Secretary may not modify by regulation the formula established under sections 447.331 through 447.334 of title 42, Code of Federal Regulations, in effect on November 5, 1990, to reduce the limits described in subparagraph (A).

(2) Special rule

If a State is not in compliance with the regulations described in paragraph (1)(B), paragraph (1)(A) shall not apply to such State until such State is in compliance with such regulations.

(3) Effect on State maximum allowable cost limitations

This section shall not supersede or affect provisions in effect prior to January 1, 1991, or after December 31, 1994, relating to any maximum allowable cost limitation established by a State for payment by the State for covered outpatient drugs, and rebates shall be made under this section without regard to whether or not payment by the State for such drugs is subject to such a limitation or the amount of such a limitation.

[(4)] [FN2] Establishment of upper payment limits

HCFA shall establish a Federal upper reimbursement limit for each multiple source drug for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent, regardless of whether all such additional formulations are rated as such and shall use only such formulations when determining any such upper limit.

(f) Repealed and redesignated

(1) Repealed. Pub.L. 103-66, Title XIII, § 13602(a)(1), Aug. 10, 1993, 107 Stat. 613

(2) Redesignated (e)[(4)]

(g) Drug use review

(1) In general

(A) In order to meet the requirement of section 1396b(i)(10)(B) of this title, a State shall provide, by not later than January 1, 1993, for a drug use review program described in paragraph (2) for covered outpatient drugs in order to assure that prescriptions (i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results. The program shall be designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists, and patients, or associated with specific drugs or groups of drugs, as well as potential and actual severe adverse reactions to drugs including education on therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse.

(B) The program shall assess data on drug use against predetermined standards, consistent with the following:

(i) compendia which shall consist of the following:

(I) American Hospital Formulary Service Drug Information;

(II) United States Pharmacopeia-Drug Information;

(III) the DRUGDEX Information System; and

(IV) American Medical Association Drug Evaluations; and

(ii) the peer-reviewed medical literature.

(C) The Secretary, under the procedures established in section 1396b of this title, shall pay to each State an amount equal to 75 per centum of so much of the sums expended by the State plan during calendar years 1991 through 1993 as the Secretary determines is attributable to the statewide adoption of a drug use review program which conforms to the requirements of this subsection.

(D) States shall not be required to perform additional drug use reviews with respect to drugs dispensed to residents of nursing facilities which are in compliance with the drug regimen review procedures prescribed by the Secretary for such facilities in regulations implementing section 1396r of this title, currently at section 483.60 of title 42, Code of Federal Regulations.

(2) Description of program

Each drug use review program shall meet the following requirements for covered outpatient drugs:

(A) Prospective drug review

(i) The State plan shall provide for a review of drug therapy before each prescription is filled or delivered to an individual receiving benefits under this subchapter, typically at the point-of-sale or point of distribution. The review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with nonprescription or over- the-counter drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Each State shall use the compendia and literature referred to in paragraph (1)(B) as its source of standards for such review.

(ii) As part of the State's prospective drug use review program under this subparagraph applicable State law shall establish standards for counseling of individuals receiving benefits under this subchapter by pharmacists which includes at least the following:

(I) The pharmacist must offer to discuss with each individual receiving benefits under this subchapter or caregiver of such individual (in person, whenever practicable, or through access to a telephone service which is toll-free for long-distance calls) who presents a prescription, matters which in the exercise of the pharmacist's professional judgment (consistent with State law respecting the provision of such information), the pharmacist deems significant including the following:

(aa) The name and description of the medication.

(bb) The route, dosage form, dosage, route of administration, and duration of drug therapy.

(cc) Special directions and precautions for preparation, administration and use by the patient.

(dd) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.

(ee) Techniques for self-monitoring drug therapy.

(ff) Proper storage.

(gg) Prescription refill information.

(hh) Action to be taken in the event of a missed dose.

(II) A reasonable effort must be made by the pharmacist to obtain, record, and maintain at least the following information regarding individuals receiving benefits under this subchapter:

(aa) Name, address, telephone number, date of birth (or age) and gender.

(bb) Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.

(cc) Pharmacist comments relevant to the individuals [FN3] drug therapy.

Nothing in this clause shall be construed as requiring a pharmacist to provide consultation when an individual receiving benefits under this subchapter or caregiver of such individual refuses such consultation.

(B) Retrospective drug use review

The program shall provide, through its mechanized drug claims processing and information retrieval systems (approved by the Secretary under section 1396b(r) of this title) or otherwise, for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists and individuals receiving benefits under this subchapter, or associated with specific drugs or groups of drugs.

(C) Application of standards

The program shall, on an ongoing basis, assess data on drug use against explicit predetermined standards (using the compendia and literature referred to in subsection (1)(B) as the source of standards for such assessment) including but not limited to monitoring for therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, and clinical abuse/misuse and, as necessary, introduce remedial strategies, in order to improve the quality of care and to conserve program funds or personal expenditures.

(D) Educational program

The program shall, through its State drug use review board established under paragraph (3), either directly or through contracts with accredited health care educational institutions, State medical societies or State pharmacists associations/ societies or other organizations as specified by the State, and using data provided by the State drug use review board on common drug therapy problems, provide for active and ongoing educational outreach programs (including the activities described in paragraph (3)(C)(iii) of this subsection) to educate practitioners on common drug therapy problems with the aim of improving prescribing or dispensing practices.

(3) State drug use review board

(A) Establishment

Each State shall provide for the establishment of a drug use review board (hereinafter referred to as the "DUR Board") either directly or through a contract with a private organization.

(B) Membership

The membership of the DUR Board shall include health care professionals who have recognized knowledge and expertise in one or more of the following:

(i) The clinically appropriate prescribing of covered outpatient drugs.

(ii) The clinically appropriate dispensing and monitoring of covered outpatient drugs.

(iii) Drug use review, evaluation, and intervention.

(iv) Medical quality assurance.

The membership of the DUR Board shall be made up at least 1/3 but no more than 51 percent licensed and actively

practicing physicians and at least 1/3 * * * licensed and actively practicing pharmacists.

(C) Activities

The activities of the DUR Board shall include but not be limited to the following:

(i) Retrospective DUR as defined in section (2)(B).

(ii) Application of standards as defined in section (2)(C).

(iii) Ongoing interventions for physicians and pharmacists, targeted toward therapy problems or individuals identified in the course of retrospective drug use reviews performed under this subsection. Intervention programs shall include, in appropriate instances, at least:

(I) information dissemination sufficient to ensure the ready availability to physicians and pharmacists in the State of information concerning its duties, powers, and basis for its standards;

(II) written, oral, or electronic reminders containing patient-specific or drug-specific (or both) information and suggested changes in prescribing or dispensing practices, communicated in a manner designed to ensure the privacy of patient-related information;

(III) use of face-to-face discussions between health care professionals who are experts in rational drug therapy and selected prescribers and pharmacists who have been targeted for educational intervention, including discussion of optimal prescribing, dispensing, or pharmacy care practices, and follow-up face-to-face discussions; and

(IV) intensified review or monitoring of selected prescribers or dispensers.

The Board shall re-evaluate interventions after an appropriate period of time to determine if the intervention improved the quality of drug therapy, to evaluate the success of the interventions and make modifications as necessary.

(D) Annual report

Each State shall require the DUR Board to prepare a report on an annual basis. The State shall submit a report on an annual basis to the Secretary which shall include a description of the activities of the Board, including the nature and scope of the prospective and retrospective drug use review programs, a summary of the interventions used, an assessment of the impact of these educational interventions on quality of care, and an estimate of the cost savings generated as a result of such program. The Secretary shall utilize such report in evaluating the effectiveness of each State's drug use review program.

(h) Electronic claims management

(1) In general

In accordance with chapter 35 of Title 44 (relating to coordination of Federal information policy), the Secretary shall encourage each State agency to establish, as its principal means of processing claims for covered outpatient drugs under this subchapter, a point-of-sale electronic claims management system, for the purpose of performing on-line, real time eligibility verifications, claims data capture, adjudication of claims, and assisting pharmacists (and other authorized persons) in applying for and receiving payment.

(2) Encouragement

In order to carry out paragraph (1)--

(A) for calendar quarters during fiscal years 1991 and 1992, expenditures under the State plan attributable to development of a system described in paragraph (1) shall receive Federal financial participation under section

1396b(a)(3)(A)(i) of this title (at a matching rate of 90 percent) if the State acquires, through applicable competitive procurement process in the State, the most cost-effective telecommunications network and automatic data processing services and equipment; and

(B) the Secretary may permit, in the procurement described in subparagraph (A) in the application of part 433 of title 42, Code of Federal Regulations, and parts 95, 205, and 307 of title 45, Code of Federal Regulations, the substitution of the State's request for proposal in competitive procurement for advance [FN4] planning and implementation documents otherwise required.

(i) Annual report

(1) In general

Not later than May 1 of each year the Secretary shall transmit to the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and the House of Representatives a report on the the [FN5] operation of this section in the preceding fiscal year.

(2) Details

Each report shall include information on--

(A) ingredient costs paid under this subchapter for single source drugs, multiple source drugs, and nonprescription covered outpatient drugs;

(B) the total value of rebates received and number of manufacturers providing such rebates;

(C) how the size of such rebates compare with the size or rebates offered to other purchasers of covered outpatient drugs;

(D) the effect of inflation on the value of rebates required under this section;

(E) trends in prices paid under this subchapter for covered outpatient drugs; and

(F) Federal and State administrative costs associated with compliance with the provisions of this subchapter.

(j) Exemption of organized health care settings

(1) Covered outpatient drugs dispensed by health maintenance organizations, including medicaid managed care organizations that contract under section 1396b(m) of this title, are not subject to the requirements of this section.

(2) The State plan shall provide that a hospital (providing medical assistance under such plan) that dispenses covered outpatient drugs using drug formulary systems, and bills the plan no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the State plan) shall not be subject to the requirements of this section.

(3) Nothing in this subsection shall be construed as providing that amounts for covered outpatient drugs paid by the institutions described in this subsection should not be taken into account for purposes of determining the best price as described in subsection (c) of this section.

(k) Definitions

In this section--

(1) Average manufacturer price

The term "average manufacturer price" means, with respect to a covered outpatient drug of a manufacturer for a rebate

period, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts.

(2) Covered outpatient drug

Subject to the exceptions in paragraph (3), the term "covered outpatient drug" means--

(A) of those drugs which are treated as prescribed drugs for purposes of section 1396d(a)(12) of this title, a drug which may be dispensed only upon prescription (except as provided in paragraph (5)), and--

(i) which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 355 or 357] or which is approved under section 505(j) of such Act [21 U.S.C.A. § 355(j)];

(ii) (I) which was commercially used or sold in the United States before October 10, 1962, or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug; and (II) which has not been the subject of a final determination by the Secretary that it is a "new drug" (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 321(p)]) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act [21 U.S.C.A. § 331, 332(a), or 334(a)] to enforce section 502(f) or 505(a) of such Act [21 U.S.C.A. § 352(f) or 355(a)]; or

(iii) (I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 355(e)] on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling; and

(B) a biological product, other than a vaccine which--

(i) may only be dispensed upon prescription,

(ii) is licensed under section 262 of this title, and

(iii) is produced at an establishment licensed under such section to produce such product; and

(C) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 356].

(3) Limiting definition

The term "covered outpatient drug" does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this subchapter as part of payment for the following and not as direct reimbursement for the drug):

(A) Inpatient hospital services.

(B) Hospice services.

(C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs.

(D) Physicians' services.

(E) Outpatient hospital services.

(F) Nursing facility services and services provided by an intermediate care facility for the mentally retarded.

(G) Other laboratory and x-ray services.

(H) Renal dialysis.

Such term also does not include any such drug or product for which a National Drug Code number is not required by the Food and Drug Administration or a drug or biological [FN6] used for a medical indication which is not a medically accepted indication. Any drug, biological product, or insulin excluded from the definition of such term as a result of this paragraph shall be treated as a covered outpatient drug for purposes of determining the best price (as defined in subsection (c)(1)(C) of this section) for such drug, biological product, or insulin.

(4) Nonprescription drugs

If a State plan for medical assistance under this subchapter includes coverage of prescribed drugs as described in section 1396d(a)(12) of this title and permits coverage of drugs which may be sold without a prescription (commonly referred to as "over-the-counter" drugs), if they are prescribed by a physician (or other person authorized to prescribe under State law), such a drug shall be regarded as a covered outpatient drug.

(5) Manufacturer

The term "manufacturer" means any entity which is engaged in--

(A) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or

(B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

(6) Medically accepted indication

The term "medically accepted indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.], or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section.

(7) Multiple source drug; innovator multiple source drug; noninnovator multiple source drug; single source drug

(A) Defined

(i) Multiple source drug

The term "multiple source drug" means, with respect to a rebate period, a covered outpatient drug (not including any drug described in paragraph (5)) for which there are 2 or more drug products which--

(I) are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations"),

(II) except as provided in subparagraph (B), are pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C) and as determined by the Food and Drug Administration, and

(III) are sold or marketed in the State during the period.

(ii) Innovator multiple source drug

The term "innovator multiple source drug" means a multiple source drug that was originally marketed under an original new drug application approved by the Food and Drug Administration.

(iii) Noninnovator multiple source drug

The term "noninnovator multiple source drug" means a multiple source drug that is not an innovator multiple source drug.

(iv) Single source drug

The term "single source drug" means a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributers [FN7] operating under the new drug application.

(B) Exception

Subparagraph (A)(1)(II) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (A)(1)(I), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C).

(C) Definitions

For purposes of this paragraph--

(i) drug products are pharmaceuutically [FN8] equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity;

(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence; and

(iii) a drug product is considered to be sold or marketed in a State if it appears in a published national listing of average wholesale prices selected by the Secretary, provided that the listed product is generally available to the public through retail pharmacies in that State.

(8) Rebate period

The term "rebate period" means, with respect to an agreement under subsection (a) of this section, a calendar quarter or other period specified by the Secretary with respect to the payment of rebates under such agreement.

(9) State agency

The term "State agency" means the agency designated under section 1396a(a)(5) of this title to administer or supervise the administration of the State plan for medical assistance.

CREDIT(S)

1999 Electronic Update

(Aug. 14, 1935, c. 531, Title XIX, § 1927, as added Nov. 5, 1990, Pub.L. 101- 508, Title IV, § 4401(a)(3), 104 Stat. 1388-143, and amended Nov. 4, 1992, Pub.L. 102-585, Title VI, § 601(a) to (c), 106 Stat. 4962 to 4964; Apr. 12, 1993, Pub.L. 103-18, § 2(a), 107 Stat. 54; Aug. 10, 1993, Pub.L. 103-66, Title XIII, § 13602(a), 107 Stat. 613; Aug. 5, 1997, Pub.L. 105-33, Title IV, §§ 4701(b)(2)(A)(x), 4756, 111 Stat. 493, 527.)

[FN1] So in original. A comma probably should appear here.

[FN2] So in original. See Codification note under this section.

[FN3] So in original. Probably should be "individual's".

[FN4] So in original. Probably should be "advanced".

[FN5] So in original. The second "the" probably should not appear.

[FN6] So in original. Probably should be "biological product".

[FN7] So in original. Probably should be "distributors".

[FN8] So in original. Probably should be "pharmaceutically".

<General Materials (GM) - References, Annotations, or Tables>